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PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER NJ 07936-1080

**MAILED**

**JUN 19 2009**

In re Patent No. 7,470,792	:	
Koch et al.	:	
Issue Date: December 30, 2008	:	
Application No. 10/526,283	:	DECISION ON REQUEST FOR
Filed: September 1, 2005	:	RECONSIDERATION OF
Attorney Dkt. No. ON/4-32671A	:	PATENT TERM ADJUSTMENT
Title: Process For The	:	
Preparation of Epothilone	:	
Derivatives, New Epothilone	:	
Derivatives As Well As New	:	
Intermediate Products For the	:	
Process and The Methods of	:	
Preparing Same	:	

**OFFICE OF PETITIONS**

This is in response to the "Application for Patent Term Adjustment-Post-Grant" filed February 13, 2009. This petition will be treated under 37 CFR 1.705(d).

The application for reconsideration of patent term adjustment is **GRANTED** to the extent indicated herein.

On December 30, 2008, the above-identified application matured into US Patent No. 7,470,792 with a patent term adjustment of 131 days. This request for reconsideration of patent term adjustment (including the required fee) was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentee requests recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under 35 U.S.C. §154(b)(1)(A) overlaps with a delay under 35 U.S.C. §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), 120 days, does not overlap with the 131

day period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), as these periods do not occur on the same day.

Thus, patentee requests that the determination of patent term adjustment be increased by 120 days to a total of two hundred fifty-one (251) days.

The 251 day period is calculated based on the application having been filed under 35 U.S.C. §371 on September 1, 2005, and the issuance of the patent on December 30, 2008.

Accordingly, the period of adjustment under § 1.702(b) is 120 days, counting the number of days beginning on September 1, 2008 and ending on December 30, 2008.

The 205 day period is for failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 371, pursuant to § 1.702(a)(1). A restriction requirement was mailed on May 25, 2007, which is 14 months and 205 days after the application was filed on September 1, 2005.

Patentee agrees that the total period of Office delay is the sum of the period of Three Years Delay terminated with the issuance of the patent and the period of Examination Delay to the extent that these periods of delay are not overlapping.

Patentee contends that the 120 days of the period of delay do not overlap with the 131 days.

Accordingly, patentees submit that the total period of Office Delay is 325 days, which is the sum of the period of Three Year Delay (120 days) and the period of Examination Delay (205 days).

As such, patentees assert entitlement to a patent term adjustment of 251 days ( $120 + 205 - 74$  for applicant delay).

Under 37 CFR § 1.703(f), patentee is entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which applicants failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay

reduced by the period of applicant delay. The period of reduction of 74 days for applicant delay is not in dispute.

However, since this application was filed pursuant to 35 U.S.C. §371 the three-year delay is calculated based upon the date of commencement of the application. In this instance the date of commencement is March 13, 2005. Thus the application was pending three years and 292 days after the commencement date. The Office agrees that because certain actions were not taken within specified time frames, the patent is entitled to an adjustment of 205 days pursuant to 37 CFR 1.702(a). At issue is whether patentees should accrue an additional 292 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 205 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 205 of the 292 days overlap. Patentee's calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of applicants. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing or commencement date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718<sup>1</sup>

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing or commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, September 1, 2005 to December 30, 2008 (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). 205 days of patent term adjustment were

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<sup>1</sup> The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

accorded prior to the issuance of the patent for the Office failing to respond within a specified time frame. Otherwise, the Office took all actions set forth in 37 C.F.R. § 1.702(a) within the prescribed timeframes. The 205 days accorded pursuant to 37 CFR 1.702(a) overlap with the 292 days of Office delay under 37 CFR 1.702(b).

The application actually issued three years and 292 days after its commencement date. The Office did not delay 205 days and then delay an additional 292 days.

Accordingly, the proper adjustment of 292 days of patent term adjustment (not 205 days and 292 days) should have been entered because the period of delay of 205 of 292 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 205 days attributable to grounds specified in § 1.702(a). Entry of both periods is not warranted. Thus, 292 days, which includes the 205 days pursuant to 37 CFR 1.702(a), is determined to be the actual number of days that the issuance of the patent was delayed.

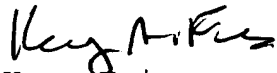
In view thereof, the patent term adjustment indicated in the patent should have been two hundred eighteen (218) days (292 - 74 applicant delay).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond to this decision. No extensions of time will be granted under § 1.136.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. See 35 U.S.C. § 254 and 37 CFR § 1.322. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by two hundred eighteen (218) days.

Telephone inquiries specific to this matter should be directed to Charlema Grant, Petitions Attorney, at (571) 272-3215.

A handwritten signature in black ink, appearing to read "Kery M. Fries". The signature is written in a cursive, slightly stylized font.

Kery Fries

Senior Legal Advisor Attorney

Office of Patent Legal Administration

Office of Deputy Commissioner

For Patent Examination Policy

Day : Wednesday

Date: 6/17/2009

Time: 12:01:23

**PALM INTRANET****PTA Calculations for Application: 10/526283**

Application Filing Date:	09/01/2005	PTO Delay (PTO):	205
Issue Date of Patent:	12/30/2008	Three Years:	0
Pre-Issue Petitions:	0	Applicant Delay (APPL):	74
Post-Issue Petitions:	0	Total PTA (days):	218
PTO Delay Adjustment:	87		

**File Contents History**

Number	Date	Contents Description	PTO	APPL	START
48	06/17/2009	ADJUSTMENT OF PTA CALCULATION BY PTO	87		
44.5	12/10/2008	PTA 36 MONTHS			
44	12/30/2008	PATENT ISSUE DATE USED IN PTA CALCULATION			
43	11/27/2008	EXPORT TO FINAL DATA CAPTURE			
42	11/26/2008	DISPATCH TO FDC			
41	11/26/2008	APPLICATION IS CONSIDERED READY FOR ISSUE			
40	11/25/2008	ISSUE FEE PAYMENT VERIFIED			
39	11/25/2008	ISSUE FEE PAYMENT RECEIVED			
38	11/17/2008	FINISHED INITIAL DATA CAPTURE			
37	08/29/2008	EXPORT TO INITIAL DATA CAPTURE			
36	08/26/2008	MAIL NOTICE OF ALLOWANCE			
35	08/25/2008	ISSUE REVISION COMPLETED			
34	08/25/2008	DOCUMENT VERIFICATION			
33	08/25/2008	NOTICE OF ALLOWANCE DATA VERIFICATION COMPLETED			
32	08/25/2008	NOTICE OF ALLOWABILITY			
28	05/07/2008	INFORMATION DISCLOSURE STATEMENT CONSIDERED			
27	05/07/2008	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		0	25
26	06/18/2008	DATE FORWARDED TO EXAMINER			
25	05/07/2008	RESPONSE AFTER NON-FINAL ACTION			
24	05/07/2008	INFORMATION DISCLOSURE STATEMENT (IDS) FILED			
23	02/08/2008	MAIL NON-FINAL REJECTION			
22	02/04/2008	NON-FINAL REJECTION			



19	03/22/2006	INFORMATION DISCLOSURE STATEMENT CONSIDERED			
18	11/20/2007	DATE FORWARDED TO EXAMINER			
17	11/07/2007	RESPONSE TO ELECTION / RESTRICTION FILED		74	15
16	11/07/2007	REQUEST FOR EXTENSION OF TIME - GRANTED			
15	05/25/2007	MAIL RESTRICTION REQUIREMENT	205		-1
14	05/24/2007	REQUIREMENT FOR RESTRICTION / ELECTION			
13	09/14/2006	CASE DOCKETED TO EXAMINER IN GAU			
12	09/12/2006	IFW TSS PROCESSING BY TECH CENTER COMPLETE			
11.7	03/22/2006	INFORMATION DISCLOSURE STATEMENT (IDS) FILED			
11	03/22/2006	INFORMATION DISCLOSURE STATEMENT (IDS) FILED			
10	02/09/2006	CLEARED BY OIPE CSR			
9	02/09/2006	CLEARED BY OIPE CSR			
8	02/08/2006	CLEARED BY OIPE CSR			
7	09/01/2005	371 COMPLETION DATE			
6	01/26/2006	APPLICATION DISPATCHED FROM OIPE			
5	01/26/2006	NOTICE OF DO/EO ACCEPTANCE MAILED			
4	09/01/2005	ADDITIONAL APPLICATION FILING FEES			
3	09/01/2005	A STATEMENT BY ONE OR MORE INVENTORS SATISFYING THE REQUIREMENT UNDER 35 USC 115, OATH OF THE APPLIC			

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#### EXPLANATION OF PTA CALCULATION

#### EXPLANATION OF PTE CALCULATION

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UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT : 7,470,792 B2

DATED : December 30, 2008

INVENTOR(S) : Koch et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[\*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (131) days

Delete the phrase "by 131 days" and insert – by 218 days--